

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 25

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Ex parte STAN CIPKOWSKI

**MAILED**

Appeal No. 2001-2522  
Application No. 08/981,665

**MAR 31 2003**

**PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES**

**ON BRIEF**

Before ADAMS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

**VACATUR AND REMAND**

This appeal involves the examiner's rejection of claims 16-19, all of the claims remaining. Claim 16 is representative and reads as follows:

16. A drug of abuse immunoassay test card for testing of fluid samples in a container having an open top and comprising a thin flat member having a rectangular outline and having front and rear surfaces, said thin flat member having a longitudinal dimension extending between top and bottom ends defining a length and having a width less than said length, and being shaped to be insertable longitudinally into a container to contact a fluid sample therein, one or more immunoassay test strips each having thereon immunoassay means to visually indicate presence or absence of a selected drug of abuse disposed longitudinally side-by-side in parallel within said thin flat member and enclosed between said front and rear surfaces, each said one or more test strips having a bottom end defining a sample receiving portion and further having a test portion spaced longitudinally therefrom wherein, in use, the fluid sample moves by capillary action to the test portion at which the presence or absence of the

selected drug of abuse in the fluid sample is visually indicated, the bottom end of each said one or more test strips being disposed at the bottom end of said thin flat member but spaced from the bottom end of said thin flat member, the top end of each said one or more test strips being spaced from the top end of said thin flat member, said front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample receiving and test portions of each of said one or more test strips.

The examiner relies on the following references:

Boger et al. (Boger)	4,518,565	May 21, 1985
Davis	5,119,830	Jun. 09, 1992
Sun et al. (Sun)	5,238,652	Aug. 24, 1993
Lee-Own et al. (Lee-Own)	5,500,375	Mar. 19, 1996
Huang et al. (Huang)	5,712,172	Jan. 27, 1998

Claims 16-19 stand rejected under 35 U.S.C. § 103 as obvious over the combination of Sun, Boger, Huang, and either of Davis or Lee-Own.

For the reasons discussed below, we vacate the rejection of record and remand for further consideration.

#### Discussion

The claims are directed to an immunoassay test card for detecting the presence of drugs of abuse in bodily fluids, especially urine. See the specification, page 3. Claim 16 is directed to a test card comprising, among other things, a "thin flat member" having at least one immunoassay test strip disposed within it, "[the] front surface of said thin flat member having a plurality of openings therein to register with and expose each of the sample receiving and test portions of each of said one or more test strips."

The examiner rejected the claims as obvious over the disclosures of Sun, Boger, and Huang, combined with either of Davis or Lee-Own. The examiner

apparently considered Sun to be the closest prior art, although he acknowledged that Sun's immunoassay device did not include "openings exposing the test portions of the strips." See the Examiner's Answer, page 6: "In contrast to the invention as instantly claimed, the reference teaches moisture impervious housing(s), such as welded plastics, for supporting the membrane strips, each housing having an opening for introduction of a body fluid sample . . . , rather than alternative supports also having openings exposing the test portions of the strips."

The examiner, apparently relying on the secondary references to meet this limitation of the claims, then reviewed the disclosures of Boger, Huang, Davis, and Lee-Own. See the Examiner's Answer, pages 6-8. He concluded that it

would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have supported the test strips of Sun et al[.] on any known and conventional alternative support/holder, such as those taught by Boger et al[.] or Huang et al[.], because one would have had ample motivation to select from known and conventional alternative support/holder components with the expectation that such a known support would perform its desired support/holder function. . . . It would have been further obvious to have provided the support/holder of Sun et al[.] in view of Boger et al[.] with windows, openings, gaps, or holes for sample application and viewing, as is conventional and required for such supports/holders in order to apply sample to the test strips and view results on the test strips, especially immunoassay test strips, as taught by any of Boger et al[.], Huang et al[.], Lee-Own et al[.], or Sun et al.

Examiner's Answer, pages 8-9 (emphasis added).

We conclude that the rejection does not provide us with an adequate basis for review. We therefore vacate the rejection of record and remand the

application to the examiner for further consideration. The following issues need to be considered and addressed on the record.

First, the claims should be clearly construed. “[N]ot unlike a determination of infringement, a determination of anticipation, as well as obviousness, involves two steps. First is construing the claim, . . . followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art.” Key Pharm. Inc. v. Hercon Labs. Corp., 161 F.3d 709, 714, 48 USPQ2d 1911, 1915 (Fed. Cir. 1998). In particular, the examiner should provide an on-the-record interpretation of the claim limitation reciting “a plurality of openings [to] expose each of the sample receiving and test portions” of the test strips.

It is unclear from the Examiner’s Answer how the examiner construed this limitation of the claims. On the one hand, he stated that Sun differed from the claimed device because Sun’s device lacked “openings exposing the test portions of the strips.” Examiner’s Answer, page 6. On the other hand, he concluded that this limitation was made obvious by the secondary references because it would have been obvious to provide “windows, openings, gaps, or holes for sample application and viewing.” Examiner’s Answer, page 9.

It is unclear whether the examiner is interpreting the claim term “openings” to be limited to physical holes or gaps, or whether the term is also read to include “windows,” i.e., an opening in one material covered by a different (transparent) material. This issue is particularly important in this case because Appellant argues that Sun differs from the claimed test card in that “[no] portion of test strip 102 is exposed to the atmosphere to provide a visual indication of the test results

102  
claims

until an outside sleeve 105 is moved longitudinally to reveal a view window area."

Appeal Brief, page 6.

Thus, Appellant seems to be implicitly interpreting the claims to require an opening that exposes the test results not just to the view of an observer but "to the atmosphere;" i.e., a hole as opposed to a window. In addition, Appellant appears to interpret the claims to require that the opening be present without any action by the user, such as moving an outside sleeve longitudinally to reveal a view window area. It is unclear from the record both whether these interpretations are reasonable and whether the examiner agrees with them.

"It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification." In re Sneed, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983). "[A] claim must be read in view of the specification of which it is a part." Renishaw plc v. Marposs Societa per Azioni, 158 F.3d 1243, 1248, 48 USPQ2d 1117, 1120 (Fed. Cir. 1998). "Likewise, any interpretation that is provided or disavowed in the prosecution history also shapes the claim scope." Id. at 1249 n.3, 48 USPQ2d at 1121 n.3. "Ultimately, the interpretation to be given a [claim] term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." Id. at 1250, 48 USPQ2d at 1122.

On return of this application, the examiner should interpret the scope and meaning of the claims, particularly the claim terms "opening" and "expose." In doing so, the examiner should consider the terms in light of any art-accepted usage and any guidance provided by the specification. In particular, the examiner should consider the paragraph bridging pages 11-12 of the specification, which states:

A modification of the test card is shown at 44 in Fig. 9. In this modification, the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings. . . . The top and bottom plys may be of a thin vinyl sheet or cardboard coated with plastic. The top ply 47 is provided with a plurality of test windows 50 through which the test results as indicated by the test strips can be seen. At the lower end of the card are provided sample openings 51 through with the liquid test specimen is able to contact the absorbent or sample portions of the test strips.

(Emphasis added.) The specification also describes "a modification of the test card 44 in which the card is made of three separate plys which are then laminated. . . . The top ply 47 similarly has the test openings or windows 50 and the sample openings 51 and the bottom ply 46 is solid." Page 12, first full paragraph.

The examiner should also consider Appellant's apparent interpretation that the claims require an opening "exposed to the atmosphere," and do not encompass a feature such as in Sun's device, where "an outside sleeve [must be] moved longitudinally to reveal a view window area." After construing the claims, the examiner should consider whether the references (e.g., Sun) disclose or suggest all of the claim limitations, as properly construed, either alone or in combination.

Summary

The claims must be construed to determine what, if any, differences exist between the claimed device and those of the prior art. Upon return of this case, the examiner should construe the limitations of the claims and take whatever action is appropriate in view of that claim construction.

VACATED and REMANDED



Donald E. Adams	)	
Administrative Patent Judge	)	
	)	
	)	
Demetra J. Mills	)	BOARD OF PATENT
Demetra J. Mills	)	
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